

Object/Subject
KION Anesthesia System –510(k) Summary & CertificationDoc-ID
EVU-111 053Issue no.
- 00**510 (k) Summary**
as required by section 807.92(c)**K 010923****JAN 23 2002****Subscribers Name & Address**

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Trade Name

KION Anesthesia System-Pressure Control Functionality

Device Classification

<i>Common Name</i>	<i>Classification Number</i>	<i>Class</i>	<i>Regulation Number</i>
Gas machine, Anesthesia	73 BSZ	II	21 CFR 868.5160
Gas machine, Analgesia	73 ELI	II	21 CFR 868.5160
Arrhythmia Detector and Alarm	74 DSI	III	21 CFR 870.1025
Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms)	MXH	III	21 CFR 870.1025

Predicate Device Identification

<i>Legally marketed devices to which equivalence is being claimed</i>	<i>510(k) #</i>
Servo Ventilator 900C	K841529
KION Anesthesia System	K973971
Modification to KION Anesthesia System	K001315

Device Description (for detailed description see Section F)

Pressure Control is a mode of ventilation intended for patients without breathing capacity. It can also be suitable for patients with a large leakage at the endotracheal tube and patients with lung compartments with different resistances and compliances.

In this mode, gas is delivered to the patient at a preset constant pressure during inspiration. The inspiratory time is determined by the setting "I:E Ratio".
The number of breaths delivered is determined by the setting "CMV Frequency".
The amount of inspiratory pressure generated is set by the "Pressure Control Level Above PEEP" setting and will be constant throughout the inspiratory phase.

The flow rate is not preset and is determined by the airway pressure and the lung compliance. Due to the constant pressure into an enclosed lung compartment, the flow pattern that results is that of a decelerating flow pattern.

A Tidal volume is not set, but rather is a result of the pressure, time and flow combination. As such tidal volumes may vary from breath to breath. This is a typical feature of Pressure Control.

Pause is not used in Pressure Controlled Ventilation and therefore expiration commences as soon as inspiration has ceased. The expiration will end when a new controlled breath starts

Intended Use of the Device:

The KION Anesthesia System is intended for general anaesthesia use. The KION Anesthesia System will deliver operator set concentrations of oxygen and anesthesia gases as well as deliver controlled breaths to the patient with either a constant or a decelerating flow pattern. KION Anesthesia System is also intended to allow for the provision of manual ventilation and spontaneous ventilation.

Intended operator:

The KION Anesthesia System is intended for use by Healthcare professionals who are trained in the administration of anesthesia

Intended Patient Populations:

The KION Anesthesia System is intended for use on the neonatal to adult patient populations in manual ventilation and pressure control mode and for use on the infant (excluding neonates) to adult patient populations in volume control mode

Intended Use Environment:

The KION Anesthesia System is intended to be used in the environments where anesthesia is to be administered by Healthcare professionals trained in administering anaesthesia.

It is not intended for transport use in ambulances or helicopters. It is not intended for use in Magnetic Resonance Imaging Suites.

Summary of technological characteristics of Device and Predicate Device:

The functionality for the KION Anesthesia System-Pressure Control Functionality is equivalent to its predicate devices the Siemens Servo Ventilator 900, 510(k) file number K841529 and KION Anesthesia System, 510(k) file numbers K973971 and K001315 .

The technical differences are a more physical dimensions, simplified user interaction for fast and reliable user operation and use of modern components for higher reliability. The technology used is assessed and the results show that KION Anesthesia System-Pressure Control Functionality has the equivalent clinical performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2002

Ms. Diane Wurzburger
Director Regulatory Affairs/Quality Assurance
Siemens-Elema AB
c/o Siemens Medical Systems, Inc.
Medical Solutions
186 Wood Avenue South
Iselin, NJ 08830-2770

Re: K010923
KION Anesthesia System – Pressure Control Functionality
Regulation Number: 868.5160 / 870.1025
Regulation Name: Monitor, Physiological, Patient (with arrhythmia detection or alarms) /
Gas Machine, Anesthesia
Regulatory Class: Class III (three)
Product Code: MHX / BSZ
Dated: December 19, 2001
Received: December 20, 2001

Dear Ms. Wurzburger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

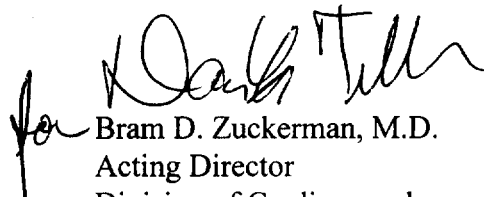
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SIEMENS

Document Type
Abbreviated 510(k)

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Object/Subject
KION Anesthesia System-Indicated Use Statement

510(k) Number (if known): K010923

Device Name: KION Anesthesia System-Pressure Control Functionality

Indications For Use:

Use of the Kion Anesthesia System is indicated in order to allow for the provision of anesthesia to the neonatal to adult patient populations in manual ventilation and pressure control mode and for use on the infant (excluding neonates) to adult patient populations in volume control mode, where patient care is provided by Healthcare professionals, trained in the administration of anesthesia, when the professional determines that a device is required assist the breathing of a patient undergoing anesthesia. The device can be used to administer anesthesia while controlling the entire ventilation for patients without any ability to breath, as well as supporting patients with reduced ability to breath.

The KION Anesthesia System is intended to be used in the environments where anesthesia is to be administered by Healthcare professionals trained in administering anaesthesia.

MRI Compatibility Statement:

Siemens KION anesthesia system is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use


Division of Cardiovascular & Respiratory Devices
510(k) Number K010923

COMPANY CONFIDENTIAL

Siemens-Elema AB
MM 0053-01

510k file (evu 111 053)